

# **EXHIBIT O**

## Confidential - Subject to Protective Order

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|---|--|
| <p>1 another Ulmsten article. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. And then 5 is data on file?</p> <p>4 A. Yes.</p> <p>5 Q. And so you had data on file at this time in</p> <p>6 April of 1999 that comparatively showed you have</p> <p>7 less complications when using the TVT versus the</p> <p>8 Burch or another procedure. That's what you're</p> <p>9 telling doctors. Right?</p> <p>10 A. Yes. I wouldn't have said that if there</p> <p>11 wasn't data on file to support that.</p> <p>12 Q. What data was it?</p> <p>13 A. I don't remember.</p> <p>14 Q. Can you think about whether it was in the</p> <p>15 form of individual follow-up with individual patients</p> <p>16 or if it was in the form of a study; do you have any</p> <p>17 idea?</p> <p>18 A. At this point, so many years later, I don't</p> <p>19 remember.</p> <p>20 Q. Now, four out of these five references that</p> <p>21 are in this are articles, and I believe all four of</p> <p>22 them are Ulmsten articles that you're citing here.</p> <p>23 Right? Let's go back and look, 1, 2, 3 and 4; are</p> <p>24 those all articles in which Ulmsten is an author?</p> <p>25 A. I believe 2, 3 and 4.</p> | <p>1 Q. And you were telling doctors that the</p> <p>2 safety of the device was very, very good with the</p> <p>3 product. Correct?</p> <p>4 A. Yes.</p> <p>5 MS. KABBASH: Objection.</p> <p>6 BY MR. CARTMELL:</p> <p>7 Q. And you were telling physicians that there</p> <p>8 were virtually no -- or there were no erosions with</p> <p>9 the device as a result of Ulmsten's studies.</p> <p>10 Correct?</p> <p>11 MS. KABBASH: Objection.</p> <p>12 THE WITNESS: I don't recall -- I would</p> <p>13 need to look at Professor Ulmsten's published</p> <p>14 studies, not all of which are listed here as</p> <p>15 references, that are relevant to that.</p> <p>16 (Marked for identification Exhibit T3369.)</p> <p>17 BY MR. CARTMELL:</p> <p>18 Q. Okay. Let me hand you what's been marked</p> <p>19 as Exhibit 3369, which is another marketing piece</p> <p>20 that we were provided in this case by defense counsel</p> <p>21 for the TVT product. Do you see on the cover it</p> <p>22 states "1, 2, 3, 4, 5 Years of Proven Performance."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. That word "proven," what does that mean?</p>   |
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| <p>1 Q. I apologize. So -- and Falconer, was he</p> <p>2 somebody that you knew when you worked there?</p> <p>3 A. I may have met Professor Falconer. I don't</p> <p>4 recall.</p> <p>5 Q. Do you know whether or not he was a paid</p> <p>6 consultant of the company?</p> <p>7 A. I don't know that.</p> <p>8 Q. At any rate, so Professor Ulmsten's studies</p> <p>9 were studies that your company was relying on</p> <p>10 routinely in marketing materials for the safety and</p> <p>11 efficacy of the TVT. Correct?</p> <p>12 A. Yes.</p> <p>13 Q. And the -- Professor Ulmsten's studies that</p> <p>14 he had done over in Europe and the data for those</p> <p>15 were sort of the cornerstone of your marketing</p> <p>16 campaign related to safety and efficacy of the TVT.</p> <p>17 Correct?</p> <p>18 MS. KABBASH: Objection.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. CARTMELL:</p> <p>21 Q. And you were telling doctors based on</p> <p>22 Professor Ulmsten's studies that efficacy for the</p> <p>23 product was high, for example, and then in the 80s to</p> <p>24 90s percentage points. Correct?</p> <p>25 A. Yes.</p>  | <p>1 A. Usually that means that there's clinical</p> <p>2 evidence to support the performance.</p> <p>3 Q. How do you prove that something has, for</p> <p>4 example, high efficacy? How do you prove it?</p> <p>5 A. Provide clinical evidence.</p> <p>6 Q. What type of evidence?</p> <p>7 A. Could be any number of different types of</p> <p>8 evidence.</p> <p>9 Q. Could evidence at a level below a</p> <p>10 randomized controlled trial prove efficacy?</p> <p>11 A. Not even a randomized control proves</p> <p>12 efficacy. However, it's, in my judgment, reasonable</p> <p>13 based on valid scientific evidence, and FDA has gone</p> <p>14 along with that, that this kind of wording is</p> <p>15 appropriate.</p> <p>16 MR. CARTMELL: Object and move to strike</p> <p>17 the answer. It wasn't responsive to my question.</p> <p>18 I'll read it again, and ask you to answer it yes or</p> <p>19 no if you can.</p> <p>20 Q. How do you prove that something has, for</p> <p>21 example, high efficacy? How do you prove it?</p> <p>22 A. That's not a yes-or-no question, obviously.</p> <p>23 Q. Actually, I withdraw that. That wasn't the</p> <p>24 question I asked you. Could evidence at a level</p> <p>25 below a randomized controlled trial prove efficacy?</p> |